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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/604,726	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10-6-06, 10-6-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the communication filed 9-14-06.

Claims 17-36 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group I, original claims 1-10, 13, 14 and 16, and SEQ ID No. 8797, in the reply filed on 9-14-06 is acknowledged. The traversal is on the ground(s) that normally ten sequences constitute a reasonable number for examination absent exceptional cases and the examiner has failed to demonstrate that the claimed sequences are an exceptional case necessitating the number to be selected be less than ten. This is not found persuasive because the searches required for proper examination of more than one sequence would unduly burden the examiner. The MPEP at 803.04 provided guidance for the number of sequences that would optionally be examined. These guidelines were written, however, before the vast expansion of the sequences in the various data bases that now must be searched, such expansion due in part to the large amount of data generated from the various genome projects. Furthermore, the searches of the appropriate data bases required for one sequence would not necessarily be coextensive with the searches required for other sequences, although some overlap might occur.

The requirement is still deemed proper and is therefore made FINAL.

Original claims 1-16 have been canceled and replaced with new claims 17-36, and claims pertaining to Groups II and III are withdrawn from further consideration

pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement with respect to single sequence requirements in the reply filed on 9-14-06.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 17, line 5, and in claim 21, line 5, the term "at least 60/85" is vague and unclear. Appropriate clarification is required.

Claim 21 is not further limiting from claim 17, and claims 22 and 23 are not further limiting from claims18 and 19, since both sets of claims encompass nucleic acids consisting of at least 18 nucleotides (e.g. of SEQ ID NO. 8797, or subsequences thereof).

In claims 29 and 30, line 1, the term "at least 12/22" is vague and unclear. Appropriate clarification is required.

In claims 35 and 36, line 1, the term "system" is vague and unclear. Appropriate clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support has been found in the specification as originally filed for the ratio "60/85" recited in claims 17 and 20, nor for the ratio "12/22" recited in claims 29 and 30, nor has support been found for the size limitations of 18-120 nucleotides, or of 18-24 (*e.g.*, as recited in claims 17-20). This is a new matter rejection. Applicant must point to support for these limitations in the original disclosure.

The claims are drawn to nucleic acids comprising SEQ ID No. 1931, SEQ ID No. 4539, and sequences that have less than 100% homology with these SEQ ID Nos (50/61 and 15/19 have been interpreted in the instant rejection to recite ratios reflecting percent identities with the recited SEQ ID Nos.).

The specification and claims do not adequately describe the genus comprising polynucleotides with variable sequences within SEQ ID Nos. 8797, 5135, 5136, 6033 or 6034, or which are capable of modulating expression of any target gene. The claims, specification and art do not adequately describe the genus comprising these nucleic acids that are at least 12/22 complementary to any binding site sequence of a target gene. The claimed genera encompass a broad array of nucleic acid molecules

(thousands of sequences), and the disclosure fails to provide a representative number of species for the broad genus or corresponding functions claimed, comprising variable sequences within 8797, 5135, 5136, 6033 or 6034, or which are capable of modulating expression of any target gene, or capable of binding an untranslated sequence of any target gene.

The specification and claims do not adequately describe the concise structural features (e.g. the nucleotide sequences) that distinguish structures within each genus from those without. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus of molecules encompassed by the variable sequences claimed. Thus, one of skill in the art would reasonably conclude that Applicant was not in possession of this broadly claimed genus.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17-36 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claims are drawn to probes, vectors and gene expression systems comprising polynucleotides between 18-120 nucleotides in length sharing at least 70% identity with SEQ ID No. 8797, or comprising at least 18 nucleotides of SEQ ID Nos.

5135, 5136, 6033, 6034, or that are at least 18/22 complementary to any binding site sequence of any target gene.

Following the requirements of the Utility Guidelines (See Federal Register, Dec. 21, 1999, Vol. 64, No. 244, *revised guidelines for Utility*), the first inquiry is whether a credible utility is cited in the specification for use of the polynucleotides. The cited utilities in the specification are that the purportedly "novel" nucleic acids claimed are sequences that have not yet been found to exist in nature, but might exist, based on various assumptions and calculations made by Applicant. The specification describes (see *e.g.* figure 7) by schematic a "'genomically programmed cell-specific protein expression modulation concept of the conceptual model of the present invention." The theory behind generating these heretofore unidentified sequences which purportedly exist as intermediates involves a bioinformatics gene detection engine 100, which is a preferred implementation of a mechanism capable of bioinformatically detecting genes of the novel groups of genes of the present invention. ...it receives three types of input, expressed RNA data 102, expressed DNA data 104, and protein function data 106, performs a complex process of analysis of this data, and based on this analysis produces output of a bioinformatically detected group of novel genes designated 108. The instant disclosure teaches an approach, therefore, of using computer calculations to predict the possibility of sequences that might exist, but which sequences have not been identified in biological systems. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. Since the polynucleotides claimed are

sequences derived from a conceptual model, and have not been identified in any biological systems, the credible utility appears to be lacking.

The next issue is whether there are any well established or substantial utilities for the claimed polynucleotides. The instant sequences are computer-generated sequences that purportedly function in the regulation of expression of a target gene in some heretofore unidentified biological context (see *e.g.*, fig 6 which illustrates a "'genomic records' concept of the conceptual model of the present invention, addressing the genomic differentiation enigma." See paragraph 0076 of the instant specification). No well established utilities for the claimed polynucleotides are identified in either the specification or in the prior art. The research contemplated by Applicant to characterize potential or purportedly naturally occurring polynucleotides that might act as intermediates in biological processes, does not constitute a specific and substantial utility. Identifying a possible polynucleotide sequence using computations or computer modeling does not define a "real world" context or use. Neither the specification as filed not any art of record discloses or suggests any property or activity for the nucleic acid compounds such that another non-asserted utility would be well established for these purported polynucleotides. There is no showing in the specification or the art that the polynucleotides claimed exist in any biological context, nor any showing of target gene binding, modulation or regulation.

Claims 17-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, substantial or asserted

utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 18, 20-22, 24, 31-34 are rejected under 35 U.S.C. 102(a) as being anticipated by Gunderson.

Gunderson (WO200216649) teaches an isolated nucleic acid consisting of 18-24 nucleotides comprising (or consisting of) at least 18 consecutive nucleotides which share at least 70% identity with SEQ ID NO. 6033, or the complement thereof (see claim 1 and p. 225; see also Accession Nos. ABQ11043 and ABQ12538 and the accompanying alignment data of Gunderson and SEQ ID No. 6033).

Claims 17, 19-21, 23, 24, 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Allawi et al.

Allawi et al (WO20019037) teach an isolated nucleic acid consisting of 18-24 nucleotides comprising (or consisting of) at least 18 consecutive nucleotides which share at least 70% identity with SEQ ID NO. 5136, or the complement thereof (see

Accession No.ADI94591 and the accompanying alignment data of Allawi et al and SEQ ID NO. 5136). *This reference was not provided because it was over 1000 pages. The reference will be supplied upon Applicant's request.*

Claims 17, 19-21, 23, 24 and 31-34 are rejected under 35 U.S.C. 102(a) as being anticipated by Gunderson.

Gunderson (WO200216649) teaches an isolated nucleic acid consisting of 18-24 nucleotides comprising (or consisting of) at least 18 consecutive nucleotides which share at least 70% identity with SEQ ID NO. 6034, or the complement thereof (see Accession No. AX443910 and the accompanying alignment data of Gunderson and SEQ ID No. 6034).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
10-26-06